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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/881,041 | 06/15/2001 | Glenn Philander Vonk | P-5013 | 5157 |

26253 7590 08/03/2010
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
1 Becton Drive
MC 110
Franklin Lakes, NJ 07417-1880

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| EXAMINER |
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SEREBOFF, NEAL

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| ART UNIT | PAPER NUMBER |
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3626

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| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

08/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/881,041
Filing Date: June 15, 2001
Appellant(s): VONK ET AL.

Stacey Longanecker, Registration Number 33, 952
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/13/2010 appealing from the Office action mailed 11/13/2009.

Art Unit: 3626

(1) Real Party in Interest

The Real part in interest in this application and appeal is Becton Dickinson and Company by an assignment recorded September 6, 2002 on Reel 013266, Frame 0424.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1 – 7

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

Art Unit: 3626

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

| | | |
|--------------|------------------|--------|
| 5,557,514 | Seare et al | 9-1996 |
| 5,867,821 | Ballantyne et al | 2-1999 |
| 5,937,387 | Summerell et al | 8-1999 |
| 6,283,761 | Joao | 9-2001 |
| 5,319,355 | Russek | 6-1944 |
| 2003/0055679 | Soll et al | 3-2003 |

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 – 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

Art Unit: 3626

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 includes the limitation, “and is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle.” The Examiner cannot find explicit, implicit or inherent support for this limitation. Claims 2 - 7 are rejected as they depend upon claim 1.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 – 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 includes, “advise the patient on how to improve the integration.”

- It is not clear from the claim exactly what the scope of the advice includes; integration improvements are subjective.
- It is further not clear who or what advises the patient. The Examiner understands that the advice is performed by the health care provider.
- The Examiner therefore understands the limitation to be non-functional descriptive information with no patentable weight. Claims 2 – 7 are rejected for the same reasons as they depend upon claim 1.

Claim Rejections - 35 USC § 103

5. ***Claims 1 – 7 are*** rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne et al. (5,867,821 ; hereinafter Ballantyne), in view of Joao (6,283,761 ; hereinafter Joao), and in view of Summerell et al. (5,937,387; hereinafter Summerell).

Art Unit: 3626

6. As per currently amended Claim 1, Ballantyne discloses a system for monitoring health-related conditions of patients, comprising:

(1) a plurality of remote monitoring stations, each being configured to receive patient health-related data pertaining to a respective patient (Ballantyne: col. 2, lines 25-26; Fig. 1-3); and

(2) a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveal population trends and outcomes, and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (Ballantyne: abstract; col. 1, line 65 - col. 2, line 63; col. 15, lines 56-65; Fig. 1-12 B).

Ballantyne, however, fails to expressly disclose a system for monitoring health-related conditions of patients, comprising:

(2) a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveal population trends and

Art Unit: 3626

outcomes, and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions

(3) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools; and

(4) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information, which relates to the selected treatment program and is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle, needs to be conveyed to the patient in response to said progress determination.

Art Unit: 3626

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Summerell. In particular, Joao and Summerell disclose a system for monitoring health-related conditions of patients, comprising:

(2) a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveal population trends and outcomes, and at least one data access device configured to provide a health care provider access to said computer network and said database (Joao: 20: 13 – 19 and 25: 13 – 19), said computer network configured (Joao: 25: 11 - 14) to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (Joao: 25:34 – 47)

(3) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30); and

Art Unit: 3626

(4) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information, which relates to the selected treatment program and is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle, needs to be conveyed to the patient in response to said progress determination (Joao: abstract; col. 4, line 26-col. 5, line 54; col. 41, line 56-col. 43, line 29; Fig. 1-15B).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne and Summerell with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

7. As per currently amended claim 2, Ballantyne discloses a system as claimed in claim 1, wherein:

(1) each of said remote monitoring stations comprises at least one measuring device, configured to measure a physiological condition of said respective patient, and to provide data representative of said physiological condition for inclusion among said patient health-related data (Ballantyne: col. 11, lines 18-27).

Ballantyne, however, fails to expressly disclose a system as claimed in claim 1, wherein:

(2) said electronic assessment tools are configured to allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program.

Nevertheless, these features are old and well known in the art, as evidenced by Summerell. In particular, Summerell discloses a system as claimed in claim 1, wherein

(2) said electronic assessment tools are configured to allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

Art Unit: 3626

8. As per currently amended claim 3, Ballantyne discloses a system as claimed in claim 1, wherein:

said remote monitoring stations are configured to provide said patient health-related data to said computer network over the Internet (Ballantyne: Fig. 1, 5, 7B)

9. As per previously presented claim 4, Ballantyne fails to expressly disclose a system as claimed in claim 1, wherein:

(1) said electronic assessment tools are quality of life assessment tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30) (Examiner has noted insofar as claim 4 recites "selected from the group consisting of Standard Form-36 (SF-36), Duke Activity Index, guidelines of the Diabetes Quality Improvement Project (DQIP), tools for specific disease state monitoring, depression scales, nutrition assessment tools, quality of life assessment tools," quality of life assessment tools is recited.).

Nevertheless, these features are old and well known in the art, as evidenced by Summerell. In particular, Summerell discloses a system as claimed in claim 1, wherein:

(1) said electronic assessment tools are quality of life assessment tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

Art Unit: 3626

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

10. As per currently amended claim 5, Ballantyne discloses a system as claimed in claim 1, wherein:

said computer network is configured to generate reports, each including health-related information pertaining to a respective said patient (Ballantyne: col. 15, lines 22-67; col. 16, lines 1-13).

11. As per currently amended claim 6, Ballantyne fails to expressly disclose a system as claimed in claim 1, wherein:

said computer network is configured to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is configured to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database.

Nevertheless, these features are old and well known in the art, as evidenced by Joao. In

particular, Joao discloses a system as claimed in claim 1, wherein:

said computer network is configured to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is configured to receive financial data pertaining to said treatment programs from said

Art Unit: 3626

organizations and to store said financial data in said database (Joao: col. 4, lines 31-47; col. 37, lines 35-47; Fig. 1).

One having ordinary skill would have found it obvious at the time of the invention to include the aforementioned features of Joao within the Ballantyne system with the motivation of facilitating the creation, management, quality, efficiency and effectiveness of healthcare services (Joao: col. 2, lines 38-54).

12. As per currently amended claim 7, Ballantyne discloses a system as claimed in claim 1, wherein:

each said remote monitoring station receives from its respective said patient said patient health-related data including data pertaining to the cardiovascular system of said patient (Ballantyne: col. 11, lines 18-27).

(10) Response to Argument

The Appellant amended claim 1, submitted 9/5/2009, to show the following limitation:

said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information, which relates to the selected treatment program and is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle, needs to be conveyed to the patient in response to said progress determination.

A. Claims 1 - 7 comply with the Written Description Requirement Under 35 U.S.C. 112, first paragraph

- The Appellant states, "Thus, the Appellants respectfully submit that the specification provides *explicit* support for information that relates to a selected treatment program and

Art Unit: 3626

is selected to advise a patient on how to improve the integration of the selected treatment program into the patient's lifestyle." (*Emphasis added*)

- The Examiner has reviewed the Appellant's citations and does not see the explicit reference.

B. Claims 1 – 7 are Definite Under 35 U.S.C. 112, second paragraph

- "Appellants submit that "to improve" the integration of a selected treatment program into one's lifestyle is readily discernable."
 - The Examiner notes the slight adjustment of the claim language within the Appellants response above. The Examiner is unsure what it means to be "selected to advise the patient on how to improve the integration." Because the improvements are subjective, the Examiner does not understand how they are therefore selected.
- "Appellants submit that the claim subsection in question recites a computer network configured with electronic assessment tools that determine whether information needs to be conveyed to the patient.
 - From the limitation above, "said computer network being configured with electronic assessment tools to allow a health care provider to..." The Examiner understands that the health care provider uses the information within the computer network.

Art Unit: 3626

- The Appellant states, “As stated above, claim 1 limitation in question is not directed to whether the patient uses the information or not, or actually improves or not, but rather to the information.”
 - The Examiner agrees. As the outcome of the information is unimportant, the information itself therefore has no function.

C. Claims 1 – 7 are Not Obvious under 35 U.S.C. 103(a) Over Ballantyne in view of Jao and further in view of Summerell

- The Appellant states, “In addition, Appellants submit that Joao fails to teach “... **determine progress** of the patient on the selected treatment program **and whether** information... **needs to be conveyed** to the patient... **in response to said progress determination**” (emphasis included)
 - As above, the Appellant has selectively edited the claim. By leaving out the introduction to this step, the Appellant argues that the computer performs these functions.
 - From the claim above, “said computer network being configured with electronic assessment tools to allow a health care provider to...”
 - The Examiner understands that the computer produces an output that allows a health care provider to analyze the data. By including the health care provider within the claim, the system functionality ends at the providing of data.

Art Unit: 3626

- The Examiner believes that the Appellant is not claiming the health care provider within the scope of the claims but merely providing the intended output of the data. Joao teaches the outputting of data to a health care provider by a computer network.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

//Neal R Sereboff//

Examiner, Art Unit 3626

Conferees:

/Robert Morgan/

Supervisory Patent Examiner, Art Unit 3626

/C. Luke Gilligan/

Primary Examiner, Art Unit 3626